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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,701	09/30/2003	Roger Petrus Gercbern Vandecruys	JAB-1467 CONT	4563
27777	7590	08/12/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			YOUNG, MICAH PAUL	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/674,701	Applicant(s) VANDECROUYS ET AL.	
	Examiner Micah-Paul Young	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 20-34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2-9-04</u> . | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 1615

DETAILED ACTION

Acknowledgment of Papers Received: preliminary Amendment and Information Disclosure

Statement filed 02/09/04.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The term "viscous" in claim 20 is a relative term which renders the claim indefinite. The term "viscous" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "viscous" is indefinite since all hydrophilic polymers can be slightly more or less viscous than another. Correction or clarification of this claim will overcome this rejection.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1615

1. Claims 20-22, 25 and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by François et al (WO 97/44039 hereafter '039). The claims are drawn to a controlled release formulation comprising 9-hydroxyrisperidone and hydrophilic polymers.
5. The '039 patent discloses a controlled release formulation comprising 9-hydroxyrisperidone and various hydrophilic polymers (abstract; page 6, lin. 7 – 35). The polymers include hydroxypropyl methylcellulose, polyvinylpyrrolidone and dextrans (page 7, lin. 7 – 17). The polymers are present in a concentration between 0.5% and 2% w/w (*Ibid.*). The reference provides a method of preparing an aqueous suspension injection (pg. 6, lin. 37 – pg. 8, lin. 15; examples). These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1615

4. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of François et al (WO 97/44039 hereafter '039) and Shimzu et al (USPN 5,824,339 hereafter '339). The claims are drawn to a formulation comprising 9-hydroxrisperidone and hydrophilic polymers. The claims recite the polymers as hydroxypropylmethylcellulose, and hydroxypropylcellulose having specific viscosities.

5. As discussed above the '039 patent discloses a formulation comprising 9-hydroxrisperidone and hydrophilic polymers. The reference however does not disclose the viscosities of the hydrophilic polymers. The '339 reference discloses antibiotics in combination with various water-soluble polymers (col. 5, lin. 9-35). The hydrophilic polymers include hydroxypropylcellulose with a viscosity between 1-150,000 cps (col. 4, lin. 55-60), and hydroxypropylmethylcellulose with a viscosity between 1-40,000 centistokes (col. 5, lin. 1-8). The formulation can comprise both celluloses at prescribed ratios (col. 6, lin. 52 – 62), in addition to further excipients such as starches and other well-known excipients. A skilled artisan would have been motivated to include the celluloses of '339 into the formulation of '039 in order to impart stability and manipulate the release of the antibiotic.

6. With these things in mind a skilled artisan would have been motivated to combine the teachings and suggestions of '039 and '339 since both formulations deliver antibiotics combined with hydrophilic cellulosic polymers. A skilled artisan would have been motivated to do so in order to impart stability and manipulate the release of the antibiotic. It would have been obvious to a skilled artisan to combine these teachings and suggestion as such with an expected result of a stable hydrophilic 9-hydroxyrisperidone formulation capable of treating various disorders.

Art Unit: 1615

7. Claims 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of François et al (WO 97/44039 hereafter '039) and Yajima et al (USPN 5,972,373 hereafter '373). The claims are drawn to a controlled release formulation comprising 9-hydroxyrisperidone and hydrophilic polymers.

8. As discussed above the '843 patent discloses a formulation comprising 9-hydroxyrisperidone and various hydrophilic polymers. The reference however is lacking a disclosure of the particular polymers of applicant.

9. The '373 patent discloses a taste masking formulation for various antibiotic agents (abstract). The formulation comprises hydrophilic polymers including hydroxypropylcellulose, hydroxypropylmethylcellulose, pregelatinized starch, and cyclodextrins (col. 3, lin. 13 – 56). Since similar antibiotics are masked by this formulation (col. 2, lin. 38-48), a skilled artisan would have been motivated to use the polymers of the '373 patent in order to impart stability and taste masking properties to the presentation.

Regarding claims that recite specific ratios and concentrations, it is the position of the examiner that such limitations do not impart patentability on the claims, since they merely represent an optimize range that can be determined through routine experimentation. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

10. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time

Art Unit: 1615

of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971). .

11. With these things in mind it would have been within the level of skill in the art to combine the antibiotic of '843 with the hydrophilic polymers of '373 in order to impart stability and taste masking properties on the formulation. A skilled artisan would make this combination with an expected result of a stable, pleasantly tasting antibiotic formulation.

12.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1615

Application/Control Number: 10/674,701

Page 7

Art Unit: 1615

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SUPERVISORY PATENT EXAMINER
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